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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,903

12/10/2004

Michael G Willits

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SYNGENTA BIOTECHNOLOGY, INC.

PATENT DEPARTMENT

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EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/517,903

Applicant(s)

WILLITS ET AL.

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 11-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action and the following **second non-final** Office Action is set forth. Applicant's amendments of claims 8-10 and withdrawal of claims 11-36 have been received and entered in full.

Claims 1-10 are under examination.

#### ***Response to Arguments***

Applicant's amendments of claims 8-10 (see page 2 of 'Amended claims' and page 6, 2<sup>nd</sup> paragraph of 'Remarks', each filed October 18, 2007) have overcome the claim objections on page 2 of the Office Action mailed July 16, 2007). The objection has been withdrawn.

Applicant's arguments, see page 6, last two lines to page 7, last paragraph of 'Remarks' filed October 18, 2007, with regard to the 35 USC 102 (b) rejection of claims 1-10 on pages 5-6 of the Office Action mailed July 16, 2007 have been fully considered and are found persuasive. The rejection has been withdrawn.

Applicant's arguments, see page 7, 2<sup>nd</sup> paragraph of 'Remarks' filed October 18, 2007, with regard to the 35 USC 102 (b) rejection of claims 1-10 on pages 6-7 of the Office Action mailed July 16, 2007 have been fully considered and are found persuasive. The rejection has been withdrawn.

#### ***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

Claims 1-10 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed July 16, 2007 (see pages 2-5). Applicant's arguments, filed October 18, 2007, have been fully considered but are not persuasive.

Applicant argues that the publication cited by the Examiner, J. Agric. Food Chem. 53: 1231-1236, 2005 was published after the filing of the instant application and cannot be considered prior art (see page 6, 1<sup>st</sup> paragraph of 'Remarks' filed October 18, 2007).

This is not persuasive. The cited reference is not being used as an art rejection, but rather to show that Applicant was not in possession of a non-transgenic domesticated *L. esculentum* plant having the claimed flavonol content even after the filing date of the instant application. The cited reference discloses flavonoid accumulation in *Lycopersicon* species, namely *L. esculentum*, *L. pennellii* v. *puberulum* and *L. esculentum* x *L. pennellii* (see page 1235, Table 2). The table shows that the non-transgenic domesticated *L. esculentum* has a flavonol content of 0.1 µg/mgdwt in the flesh; however, this is lower than the flavonol content of the claimed invention. The *L. pennellii* v. *puberulum* tomato has a flavonol content of 1.2 µg/mgdwt in the flesh; however, this is not a non-transgenic domesticated *L. esculentum* plant. Finally, the *L. esculentum* x *L. pennellii* hybrid had a flavonol content of 2 µg/mgdwt in the flesh; however, the reference discloses that the fruit from these crosses were "invariably seedless". Thus, it is unclear how Applicant was in possession of the claimed invention at the time of filing when the cited reference, which was published after the filing date of

the instant application, teaches that *L. esculentum* x *L. pennellii* hybrids are seedless. In addition, the cited reference does not teach non-transgenic domesticated *L. esculentum* having a flavonol content of 0.5 µg/mgdwt in the flesh, but instead teaches a non-transgenic domesticated *L. esculentum* having a flavonol content of 0.1 µg/mgdwt in the flesh. Though the cited reference teaches *L. pennellii* v. *puberulum* tomato and *L. esculentum* x *L. pennellii* hybrid having a flavonol content greater than of 0.5 µg/mgdwt in the flesh, neither of these is a non-transgenic domesticated *L. esculentum* tomato.

Applicant argues that the statement being cited by the Examiner was not made to suggest that the breeding process to obtain an *L. esculentum* from the F1 hybrids with the desired flavonol characteristics was not possible (see page 6, 2nd paragraph of 'Remarks' filed October 18, 2007).

This is not persuasive. The Examiner agrees that it may be possible to obtain an *L. esculentum* from the F1 hybrids with the desired flavonol characteristics; however, neither the specification nor the cited reference, which was published after the filing date of the instant application, provide any evidence of a non-transgenic domesticated *L. esculentum* having a flavonol content greater than 0.5 µg/mgdwt in the flesh. The specification states that "*L. pennellii* v. *puberulum* (LA1926) shows strong expression of all investigated flavonol biosynthetic genes in both the fruit peel and flesh...[and thus,]... *L. pennellii* v. *puberulum* (LA1926) was chosen as a crossing partner to introgress flavonol production into *L. esculentum*" (see page 10, lines 22-25); however, the specification does not show that Applicant was in possession of a non-transgenic

domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

In addition, Applicant states, "Dr. Willits and his group of researchers produced a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid, which demonstrated the transfer of the desired flavonol trait to the hybrid tomato fruit" (see page 6, 2<sup>nd</sup> paragraph of 'Remarks' filed October 18, 2007). Though this is evidence of a *L. esculentum* X *L. pennellii* v. *puberulum* hybrid having the claimed characteristics, it does not provide evidence of a non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt, which is the claimed invention.

Applicant argues that the creation of an *L. esculentum* variety maintaining the production of flavonoids in the fruit could be accomplished by any competent breeder within well known standard "ordinary skill in the art" breeding methods (see page 6, 3<sup>rd</sup> paragraph of 'Remarks' filed October 18, 2007).

This is not persuasive. The fact that an *L. esculentum* variety maintaining the production of flavonoids in the fruit could be accomplished does not provide evidence that Applicant was in possession of an *L. esculentum* variety maintaining the production of flavonoids in the fruit could be accomplished.

Applicant further states, "[a] person of ordinary skill in the art would recognize upon reading of the specification that to obtain the claimed *L. esculentum* plant, they would only need to create an *L. esculentum* X *L. pennellii* v. *puberulum* hybrid, select a progeny with the desired flavonol trait, and then develop a breeding scheme involving standard backcrossing and self-pollination methods to obtain an *L. esculentum* plant

with the desired characteristics (see page 6, 3<sup>rd</sup> paragraph of 'Remarks' filed October 18, 2007).

It should be noted that the claims are drawn to a non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt and not method of making an *L. esculentum* plant with the desired characteristics. Thus, though a person of ordinary skill in the art could possibly select progeny plants from an *L. esculentum* X *L. pennellii* v. *puberulum* hybrid that have the desired characteristics, this is not evidence that Applicant, at the time the application was filed, was in possession of a non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgwt.

The 'Willits Declaration', filed October 18, 2007, is persuasive regarding the art rejections; however, the declaration is not persuasive regarding the asserted written description of the claimed invention because a single phenotypic trait with unknown genes that are responsible for said phenotypic trait is insufficient to describe the claimed tomato plant.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Crozier et al (J. Agric. Food Chem. 45: 590-595, 1997) taken with the evidence of Mills et al (Plant Cell Reports 15: 634-636, 1996). The claims read on a non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgdwt.

Crozier et al teach tomato plants having tomato with various quercetin content (Wikipedia teaches that quercetin is a flavonoid and more specifically, a flavonol, see attached sheet). For example, see page 592, Table 1, where it discloses a cherry tomato containing up to 203 µg/g of quercetin in fresh wt.

The evidence provided by Mills et al (see page 635, Table 1) suggests that the tomato plants taught by Crozier et al would have a flavonol content in the flesh of the fruit that is greater than 0.5 µg/mgdwt.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to

Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

It would be obvious to one of ordinary skill in the art to make a non-transgenic domesticated *L. esculentum* plant having a flavonol content in the flesh of the fruit of said plant that is greater than 0.5 µg/mgdwt because Crozier et al teach “[f]lavonols...are flavonoids of particular importance as they...have been found to possess antioxidant and free radical scavenging activity (see page 590, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph).

#### ***Conclusion***

No claims allowed.

#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is (571) 272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

/Medina A. Ibrahim/  
Primary Examiner  
Art Unit 1638

January 6, 2008